

REMARKS

Examiner Teleconference

The Applicant would like to thank Examiner Erez for speaking with Applicant's representatives Kevin Farrell and Katherine Wrobel on February 19, 2010 regarding the distinguishing features between the present invention and that of the cited prior art references. Applicant gratefully thanks Examiner Erez for his instruction regarding refinement of the claims language regarding the pairing of a single bridging portion with an attached portion, replacement of "one or more connecting members" with "plurality of connecting members", and the description of a strap-like connecting member (as opposed to a thread-like connecting member). Accordingly, the independent claims now recite a "plurality" of connecting members wherein each individual connecting member comprises a single bridging and an attached portion. The independent claims as currently amended now also recite that the width of each strap-like connecting member is greater than its thickness, support for which limitation exists throughout the figures and specification, for example at paragraphs [0003] and [0014].

Rejection Under 35 USC 103(a)

Claims 1-16 and 19-34 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent Application No. 2004/0204740 to Weiser ("Weiser") in view of US Patent No. 2,798,492 to Barnes et al. ("Barnes et al.") (Because Claims 2-16 and 20-34 are dependent upon and include all limitations of Independent Claims 1 and 19, respectively, this response will address the rejection as it pertains to Independent Claims 1 and 19.) More specifically, language on page 3 of the instant Office action states that Weiser teaches every element of independent claims 1 and 19 except for narrowed bridging portions:

Weiser is silent with regards to the average width of the bridging portions being less than that of the attached portions. Instead, Weiser discloses bridging portions having the same width as the attached portions.

The Office Action proceeds with a statement that Barnes et al. cures this deficiency:

However, providing a wound closure device with bridging portions having an average width less than an attached portion is well known in the art, as shown in Fig. 2 and 5 of Barnes. Thus, Barnes discloses a bridging/attached portion arrangement that is an equivalent structure known in the art.

For the following reasons, Applicant respectfully disagrees that the proposed combination of references teaches or suggests the present invention as claimed in independent claims 1 and 19, as currently amended:

First, Applicant agrees that Weiser fails to disclose or suggest bridging portions being less than the average width of the attached portions such that the one or more first and second connecting members are sufficiently spaced-apart to facilitate fine adjustment of the first component relative to the second component for substantially parallel alignment of the edge of the first component with the edge of the second component during closure of the wound or incision. Neither the specification nor the claims of Weiser teach this limitation. The Figures of Weiser teach away from this limitation by displaying bridging portions having widths equal to that of the attached portions.

The specification further explains at paragraph [0017] that the difference in width of the bridging portion of the present invention relative to the width of the attached portion affords advantages over prior art devices in which the width of connecting members was substantially constant along their lengths. The device of Weiser presents connecting members having constant widths along their lengths. As described in specification paragraph [0014], achieving a more secure attachment in the single-width connector device of Weiser would require an increased number of connecting members that would be placed as close together as possible, thereby severely limiting adjustability. Weiser fails to teach or suggest any method for simultaneously providing a secure attachment and enabling fine adjustability.

Barnes et al. fails to cure the deficiencies of Weiser. The two –component device of Applicant's invention comprises a first and a second component which are separate and distinct from one another. Each component is applied individually to either side of the wound or incision requiring closure. By contrast, Barnes et al. teaches a single, unitary device unlike Applicant's two component device.

Applicant's interlaced two-component device offers numerous advantages over the non-component device of Barnes et al. Support for the "interlaced" limitation exists through out the Figures and at least at paragraph [0021] of the specification, reproduced here in pertinent part for convenience:

[0021]...For embodiments in which each component includes two or more connecting members, and the connecting members are attached to pulling

elements, the issue of interlacing the connecting members of the two components presents itself. This issue was discussed in US Patent No. 6,329,564, the disclosure of which is incorporated herein by reference. Briefly, in order to assemble an interlaced device it may be necessary to construct the first component and the second component independently, and subsequently cut one of the two components in order to interleave connecting members.

The use of two independently-positioned, interlaced components enables a user to precisely align distinct edges of the anchor members on either side of the wound or incision to be closed. Unlike the non-component device of Barnes et al., Applicant's two-component device provides clear visibility of the wound, and access to the wound during the closure process.

The Barnes et al. device does not have defined wound edges or even independent ends to apply. The Barnes et al. device comprises one integral unit having no distinct components and no interlaced connecting members spanning therebetween for straightening a wound edge during closure. Wounds typically take an almond shape (surface view), which shape requires a closure device to somehow move the center portion of the wound more than the ends. Barnes et al. fails to address this closure requirement. Unlike Applicant's device, the device of Barnes et al. cannot close different gap widths along the same wound. The device of Barnes et al. therefore limits any flexibility for closing the wound edges to varying degrees as would be required by a varying wound gap. The Barnes et al. device, at best, allows only for a straight pull/tension closure in a single location along the length of a wound. It cannot provide any lateral adjustment/adjustment parallel to the wound. One skilled in the art of two component wound closure devices therefore would not look to a unitary device of Barnes et al. to cure the deficiencies of Weiser.

In further support of the lateral adjustability distinction between the present invention and the proposed combination of prior art, Applicant invites the Examiner to review a product demonstration of lateral adjustability. The demonstration entitled, "Steri-Strip S Surgical Skin Closure video, App Linear 150 - Presentation/Demo (X-MS-WMV 2.2 MB)" is located at the following URL:

http://solutions9.3m.com/wps/portal/3M/en_US/IP/infectionprevention/solutions/sterilization-assurance/record-keeping/?PC_7_RJH9U5230GE3E02LECFTDQ0U54_nid=B0FMMMCZ1Pbe29FKGVD9QMgl

As indicated in the video, the almond-shaped wound is closed along its varying width by laterally adjusting the two components of the device. This is possible because of the sufficient

spacing between elongated connectors and the narrowed bridging portions. The pulling elements enable simultaneous control of the plurality of connecting members and closure of the two component device. Weiser, in contrast, requires individual closure of each elongated connector. This is evident throughout the reference and at least, for example, at FIGS 1-6, 8-9, and 11-14 and paragraphs [0041] and [0052]-[0053], reproduced here in pertinent part for convenience:

[0041] In the packaged or stored position, as shown in FIGS. 1 and 2, the bridging links 5 are folded over the upper surface 12 of the adhesive base strip 1 about a hinge 10 that is at the joint of the bridging links and base strip 1. Hinge 10 may be a hinge region formed to provide increased flexibility where bridging links 5 are joined to the base strip. As shown no adhesive is applied to the hinge region.

[0052] As shown in FIGS. 5 and 6, to close the gap 22 of wound 8, the bridging links 5a and 5b are manually pivoted from their stored position and pulled transverse to the wound lip 7.

[0053] By simultaneously exerting a force .degree. F. on pairs of adjacent bridging links 5a and 5b from opposing sides of the wound, the base strips 1a and 1b and the wound lip 7 will be drawn together to close gap 22, as shown in FIG. 6.

As indicated in these excerpts and in FIG 6, for example, individual opposing pairs of connectors, or "bridging links," are peeled off of their respective base strips, reoriented across the wound and attached to the opposing base strip. Once one pair of base strips is secured, the device prohibits any *lateral adjustment* of the wound. The Weiser device requires wound straightening *prior to* attachment of connecting members:

[0050] A typical wound 8 caused by a laceration or surgical incision is shown in FIG. 5 having a lip 7 at the edge of the gap 22. Before the closure of this invention is applied, the wound 8 is examined to determine the length L of wound 8. The base strip is then cut to a length L+which is slightly longer than wound 8. Two approximately equal lengths 1a and 1b of the base strip 1 are cut, torn or otherwise separated from the packaged closure device, as for example roll 13. After removing the outer wrap 21, edge protective tape 15 is removed to expose adhesive edge 19. In many instances the wound lip 7 will be curvilinear or otherwise of irregular shape because of natural skin tension or the nature of the injury. This may require manipulation of the skin surrounding the wound to bring the lip 7 into a substantially straight form to accommodate the straight edge 6 of base strip 1.

Weiser et al. fails to teach or suggest aligning and closing the edges of a wound or incision using the device itself and instead teaches away from this by requiring wound straightening prior to closure and attachment. Barnes et al. is limited to a straight tension–pull closure and also fails to teach or disclose a device enabling lateral adjustability to close a wound such that the wound edges are made parallel during wound closure (i.e. such that the device enables lateral adjustability.)

To further distinguish the present invention over that of the proposed combination of references and further elucidate the concept of lateral adjustability, Applicant has amended independent claims 1 and 19 to include the limitations of dependent claims 3 and 17, which introduce pulling elements attached to the plurality of connecting members. These pulling elements by design inherently enable simultaneous lateral adjustment of the connecting members during wound closure. Weiser teaches away from such pulling elements by requiring individual closure of each “bridging link.” The term “plurality” now replaces “one or more” with regard to the quantity of connecting members. Support for this limitation exists throughout the specification and at least at paragraph [0043], for example, reproduced here in pertinent part for convenience:

[0043] The two components (12 and 14) of a two-component device of the present invention (10) are shown in Fig. 1. First component (12) includes an anchoring member (16) and **a plurality of connecting members** (18) extending from a first edge of the device (20) which is also referred to herein as the wound edge. Similarly, the second component (14) includes an anchoring member (17) and **a plurality of connecting members** (19) extending from a first edge (21) of the device which is also referred to as a wound edge. [Emphasis added]

Further still, Applicant has amended independent claims 1 and 19 to recite that each of the plurality of connecting members comprises a single bridging portion and an attached portion. In other words, no attached portion is connected to more than one bridging portion. The connecting member is a unitary strap that, once attached to an anchoring member, is defined by a portion of its length attaching to the anchoring member (i.e. the “attached portion”) and a portion of its length extending over the wound (i.e. the “bridging portion”). This amendment is intending to further distinguish the present invention over embodiments with cutouts in the bridging portions. The independent claims now recite that the attachment of the connecting members to the anchoring members forms an attached portion and a single bridging

portion of each individual connecting member of the plurality of connecting members. Support for this structural limitation exists throughout the specification and figures.

Lastly, Applicant has amended the independent claims further to clearly articulate the strap-like design of the plurality of first and second connecting members. Each connecting member has a width that is greater than its thickness. Support for this limitation exists throughout the figures and specification, for example, at paragraphs [0003] and [0014], reproduced here in pertinent part for convenience:

[0003] The present invention relates to a two-component device useful for closing a laceration or incision...The connecting members are, generally speaking, elongated and strap-like in configuration. That is, the width of the connecting members is substantially greater than their thickness.

[0014] As mentioned above, the dimension of the connecting members is strap-like in that their width is substantially greater than their thickness. In light of the fact that the point of attachment between the first and second components is between the underside of attached portions of connecting members with the upper surface of attached anchoring members, maximizing the area of contact will result in a more secure closure of the device because the area of adhesive contact is maximized. Thus, from the standpoint of security of closure, wider connecting members are preferred. However, as the width of all the connecting members is increased, the distance between connecting members necessarily is decreased. It is extremely important that there be enough distance between adjacent connecting members to facilitate fine adjustment of the device as the second anchoring member is being positioned, and after the two anchoring members are positioned, but prior to fixing their relationship by attaching connecting members to anchoring members.

Unlike prior art devices comprising thread-like connecting members, such as the device described in US patent No. 2,196,296 to Flynn ("Flynn"), the strap-like connecting members of the present invention attach to their opposing anchoring members and thereby produce a more secure closure because the device is stable perpendicular to and parallel to the wound edge. The reduced width of bridging portions addresses lateral adjustability issues that would arise from closing a device with reduced spacing between strap-like connecting members. Devices such as that of Flynn never contemplate issues related to stability and attachment of connecting members and therefore never provide any motivation for features enabling lateral adjustability of strap-like connecting members that attach to anchoring members.

Applicant submits that the proposed combination of references fails to disclose or suggest the combination of features recited in independent claim 1 and Independent claim 19 as

currently amended. Because claims 2-16 and 20-34 depend respectively from the independent claims 1 and Claim 19, Applicant further submits that the proposed combination of references fails to disclose or suggest the combination of features recited in those dependent claims. Accordingly, Applicant respectfully requests withdrawal of the above-noted rejection under 35 USC 103(a).

Dependent claims 17 and 35 are rejected under 35 USC 103(a) as being unpatentable over Weiser in view of Barnes et al. and further in view of US Patent No. 5,263,970 to Preller ("Preller"). Because dependent claims 17 and 35 depend on claims 1 and 19, the following argument addresses this rejection on the independent claim level.

As indicated above, Weiser in view of Barnes fails to teach or suggest the invention as claimed in independent claims 1 and 19 as currently amended. Preller fails to cure the deficiencies of the proposed combination of references.

First, Preller teaches a unitary device instead of a device having "first and second components". Applicant respectfully points out that independent claims 1 and 19 each recite a two-component device. The two-component device comprises a first and a second component. Applicant's independent claims include the limitation that the first and second elongated connectors are interleaved, but it will be recognized that the first and second flat flexible components are separate and distinct. Applicant's use of two independently positioned components enables a user to precisely align distinct wound edges on either side of the wound or incision to be closed. Each component of Applicant's device is applied individually to either side of the wound or incision to be closed.

Preller also fails to teach or suggest that the one or more first and second elongated connectors are sufficiently spaced-apart to facilitate fine adjustment of the first flat flexible component relative to the second flat flexible component for substantially parallel alignment of the edge of the first flat flexible component with the edge of the second flat flexible component during closure of the wound or incision. Preller also fails to provide any motivation for having sufficient spacing between the connecting members so as to facilitate fine adjustment or lateral adjustability either during positioning of the second anchoring member or after the two anchoring members are positioned but prior to fixing their relationship by attaching connecting

members to anchoring members. Preller instead teaches numerous closely-spaced limbs, clearly shown without spacing in Figs. 1 and 2. Preller further describes these closely-spaced limbs as “interconnected” at column 2, lines 30-33, reproduced here:

Prior to use, the limbs 24.1 and 26.1 are interconnected along lines or zones of weakness 27 which can be ruptured to separate the limbs 24.1 and 26.1.

Not only are the limbs of Preller not sufficiently spaced apart, but they are interconnected, which precludes any spacing. Such a design, at best, highly restricts a user's ability to adjust the initially applied strips 10, 14 laterally during wound closure. Preller thereby fails to teach sufficient spacing between the limbs so as to enable any fine adjustment. Applicant's use of a two-component device having sufficiently spaced apart connecting members solves this problem associated with the cited prior art.

Applicant respectfully submits that independent claims 1 and 19 as currently amended are in condition for allowance, and Applicant accordingly requests that the Examiner reconsider and withdraw the present rejection.

Dependent claims 18 and 36 are rejected under 35 USC 103(a) as being unpatentable over Weiser in view of Barnes et al. and further in view of US Patent No. 5,979,450 to Baker (“Baker”). Applicant respectfully requests withdrawal of the present rejections. As discussed above, claims 17 and 18 and claims 35 and 36 respectively depend from Independent Claims 1 and 19, which Applicant respectfully submits are in condition for allowance. Because claims 17, 18, 35 and 36 depend from independent claims that are in condition for allowance, those dependent claims, which include all limitations of allowable independent claims, are also in condition for allowance.

Attorney Docket No. 0156-2007US01

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,

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